3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial Authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
No Requirement

AGE RESTRICTIONS:
Nasal Spray:
CENTRAL DIABETES INSIPIDUS/ARGININE VASOPRESSIN DEFICIENCY (AVP-D): 4 years of age and older
NOCTURIA/ENURESIS: 18 years of age and older

Nocdurna: 18 years of age and older

Tablets: No restriction

QUANTITY:
Primary Nocturnal Enuresis/Nocturia:
Tablet – Maximum 0.6 mg/day
Nasal spray – Maximum 40 mcg/day
Nocdurna: Females: 27.7 mcg once daily one hour before bedtime, Males: 55.3 mcg once daily one hour before bedtime

Central Diabetes Insipidus:
Tablet – Maximum 1.2 mg/day
Nasal spray– Maximum 40 mcg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral, sublingual, and intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, intranasal, sublingual

DRUG CLASS:
Vasopressin

FDA-APPROVED USES:
Desmopressin tablets: Indicated as antidiuretic replacement therapy in the management of central diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region; Indicated for the management of primary nocturnal enuresis, either alone or as an adjunct to behavioral conditioning or other non-pharmacologic intervention.
Limitation of use: Desmopressin is ineffective for the treatment of nephrogenic diabetes insipidus.

Desmopressin nasal spray (0.01%): Indicated as antidiuretic replacement therapy in the management of central diabetes insipidus in adults and pediatric patients 4 years of age and older.
Limitations of use: Desmopressin nasal spray is not indicated for treatment of nephrogenic diabetes insipidus, treatment of primary nocturnal enuresis, use in patients with conditions that compromise the intranasal route of administration (e.g., severe nasal congestion and blockage, nasal mucosa atrophy,

severe atrophic rhinitis, recent nasal surgery such as transsphenoidal hypophysectomy), use in patients with an impaired level of consciousness, use in patients requiring doses lass than 10mcg or doses that are not multiples of 10mcg.

Nocdurna*:* Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

COMPENDIAL APPROVED OFF-LABELED USES:
Desmopressin tablets for nocturia

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of desmopressin oral and nasal are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.
Contraindications to desmopressin oral and nasal include: Moderate to severe renal impairment (CrCl <50 mL/minute), hypersensitivity to desmopressin, hyponatremia or a history of hyponatremia.
Contraindications to Nocdurna include: Hyponatremia or a history of hyponatremia, renal impairment (eGFR <50 mL/minute/1.73 m2); polydipsia; concomitant use with loop diuretics or glucocorticoids (inhaled or systemic), syndrome of inappropriate antidiuretic hormone (SIADH) secretion (known or suspected); illnesses that may cause fluid or electrolyte imbalance (e.g., gastroenteritis, salt-wasting nephropathies, systemic infection); heart failure uncontrolled hypertension.

OTHER SPECIAL CONSIDERATIONS:
Nocdurna (desmopressin) sublingual tablets have a Black Boxed warning for Hyponatremia. Desmopressin can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death. Desmopressin is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids. Ensure serum sodium concentrations are normal before starting or resuming desmopressin. Measure serum sodium within 7 days and ~1 month after initiating therapy and periodically during treatment. More frequently monitor serum sodium in patients ≥65 years of age and in patients at increased risk of hyponatremia. If hyponatremia occurs, desmopressin may need to be temporarily or permanently discontinued.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
DDAVP SOLN 0.01%
DDAVP TABS 0.1MG
DDAVP TABS 0.2MG
Desmopressin Ace Spray Refrig SOLN 0.01%
Desmopressin Acetate Spray SOLN 0.01%
Desmopressin Acetate TABS 0.1MG
Desmopressin Acetate TABS 0.2MG
Nocdurna SUBL 27.7MCG
Nocdurna SUBL 55.3MCG

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Age Restrictions Quantity Place of Administration Route of Administration References	Q3 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Age Restrictions References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file